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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,069	01/03/2007	Sudeepta Aggarwal	GNE-0269 R1 (24126.156)	5360

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Arnold & Porter LLP (24126)
Attn: SV Docketing Dept.
1400 Page Mill Road
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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
11/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SV.Docketing@aporter.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,069	AGGARWAL ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-45 and 47-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-45 and 47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/9/10, 9/20/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/10 has been entered.

Applicant's arguments filed 8/9/10 have been fully considered but they are not persuasive.

Claims 1-40 and 46 have been cancelled. Claims 41-45 and 47-52 are under consideration by the examiner.

Specification

The substitute specification filed 8/9/10 has been entered.

35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-45 and 47-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 41 and 42 have been amended to be directed to a method of diagnosing a memory T cell mediated disease in a mammal. Claim 43 has been amended to be directed to a method of diagnosing a memory T cell mediated immune response in a mammal. Basis is stated to be on page 2, lines 5-23, page 144, lines 16-39, pages191-195, and Example 1. This is not agreed with. First of all, it is unclear what document applicant is pointing to (i.e. the originally filed specification or the substitute specification submitted 8/9/10.) However, neither document provides a general disclosure of diagnosing memory T cell mediated diseases or memory T cell mediated immune responses in a mammal by evaluating SEQ ID NO: 2386. The specification does not disclose that SEQ ID NOS: 2385 and/or 2386 can be used in such methods of diagnosis. The specification does **not** disclose that PRO85142 is significantly overexpressed in activated CD4+ T cells as compared to resting cells. Note that this is **not** one of the polypeptides mentioned in the last paragraph of Example 1 in the specification. There is no basis for these claims.

Claims 47-48 have been substantively amended. No basis has been pointed to for these changes and none is apparent.

Claims 41-45 and 47-52 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The specification discloses a nucleic acid molecule (SEQ ID NO:2385) encoding the polypeptide PRO85142 (SEQ ID NO:2386). The nucleic acid is contained in a clone designated as clone DNA329612. There is no disclosure of PRO85142 functional activity or pattern of expression in various tissues. There is no disclosure of proteins related to PRO85142 by either functional or sequence identity. The activity of PRO85142 polypeptide and its physical function are unknown. Expression levels of a gene encoding SEQ ID NO: 2386 is not correlated to any memory T cell mediated disease or immune response in a mammal (claims 41-43). Note that the specification discloses no **gene** encoding SEQ ID NO: 2386. SEQ ID NO: 2386 is a **cDNA**. Formation of a complex between a polypeptide comprising SEQ ID NO: 2386 and an antibody against SEQ ID NO: 2386 is not correlated to any memory T cell mediated disease in a mammal (claim 42). Note that the specification discloses no antibodies specific to SEQ ID NO: 2386 and identifies no epitopes for this protein.

It would require further experimentation and independent inventive judgment to determine if the polypeptide of SEQ ID NO: 2386, genes encoding it, or antibodies to it could be used in the claimed methods. Thus, no substantial utility has been established for the claimed methods. Identifying and studying the properties of a nucleic acid to determine if it encodes a protein and then identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. No "immediate benefit to the public" is provided based upon the information disclosed in the specification. In

all cases, experimentation on the sequence itself is required to further characterize it in order to use it in the manner disclosed.

In *Brenner v. Manson*, 148 USPQ 689, 696 (US, 1966), the Court held that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing," and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." The original disclosure lacks any successful conclusion for even one of the potential immune related diseases or inflammatory immune responses disclosed. Thus, no "substantial" or "real world" utility has been disclosed.

The limited information set forth in the specification with respect to SEQ ID NO: 2386 is insufficient to establish a specific, substantial, and credible utility for the claimed methods.

Claims 41-45 and 47-52 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicant's arguments are unpersuasive. Applicant argues that Example 1 indicates that all sequences, including SEQ ID NO: 2385, were differentially expressed and goes on to argue that this differential expression is sufficient to provide utility and enablement for the claimed methods of diagnosis. This is not agreed with. Example 1 demonstrates that (emphasis added) "**various** PRO polypeptides of the present invention are significantly differentially expressed in

isolated CD45RO activated by anti-CD3/anti-CD28 as compared to: isolated resting CD45RO, isolated resting CD45RA and isolated CD45RA activated by anti-CD3/anti-CD28 cells." This does not indicate that **all**, and in particular SEQ ID NO: 2385, were significantly differentially expressed. Example 1 does not identify SEQ ID NO: 2385 as one of the sequences significantly differentially expressed. If the change in expression was not significantly different, this provides no information to one of ordinary skill in the art with respect to the claimed methods. Note that one cannot discern from Example 1 whether or not SEQ ID NO: 2385 was overexpressed or underexpressed.

It is noted that applicant argues that the results of Example 1 are with respect to activated T cells; however, the claims are directed to memory T cells. The results of Example 1 are with respect to isolated CD45RO activated by anti-CD3/anti-CD28 and not broadly directed to all memory T cells embraced by the claims.

Applicant's references to Ponsford et al., Robinson et al., and Sen et al. are not persuasive. There is no evidence that SEQ ID NO: 2385 is significantly differentially expressed in memory T cells. The originally filed specification does not refer to these documents and does not associate their content with respect to SEQ ID NO: 2385.

Applicant's arguments with respect to subsequent identification of SEQ ID NO: 2386 as triggering receptor expressed on myeloid cells-like 2 protein (also known as TREML2 and TLT2) are unpersuasive. The specification does not disclose nor suggest any of these properties. As noted by applicant, these discoveries were made **after the priority date** of the instant application. This confirms the need for further experimentation and reinforces the position that

no real world context or use was available at the time of the invention and that the invention lacked a credible, specific, and substantial utility at the time of the invention.

On page 16 of the response, applicant states that "a simple NCBI BLAST search of the SEQ ID NO: 2386 sequence reveals that PRO85142 corresponds to TLT2 (enclosed herewith for reference)." This is not understood. No NCBI BLAST search results were attached to the response.

Again, Molloy et al. (2009) was published well after the effective filing date of the instant application. There is nothing in Molloy et al. and no evidence of record that SEQ ID NO: 2386 corresponds to TLT2 as argued by applicant. Molloy et al. does not discuss TREML2 or TLT2. Note that TREM-1 and TREM-2 are different proteins. The originally filed specification does not disclose TLT2 or the TREM family.

At the time of the invention, no credible, specific or substantial utility was known for the using the protein of SEQ ID NO:2386 in diagnosing memory T cell mediated disease or immune response. No methods of diagnosis as recited in the instant claims would have been recognized as credible, specific or substantial to those of ordinary skill in the art at the time of the invention. Applicant's arguments rely upon characterization of the protein that occurred well after the effective filing date of the invention. These studies and their results do not flow from the disclosure in the originally filed application. Research following applicant's filing date cannot remedy deficiencies in the originally filed specification and a lack of knowledge in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa